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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,336	01/10/2006	Cornelis Marius Timmers	2002.750US	8846

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ORGANON USA, INC.
PATENT DEPARTMENT
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ROSELAND, NJ 07068

EXAMINER	
O DELL, DAVID K	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,336	TIMMERS ET AL.	
	Examiner	Art Unit	
	David K. O'Dell	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 & 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *23 September 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13, 16 are pending in the current application.

2. This application is a national stage of PCT/EP03/51025 filed November 16, 2003 which claims priority to U. S. Provisional Application 60/435,040 filed December 20, 2002 and European Union Application (EPO) 2102866.7, filed December 20, 2002.

Claim Rejections - 35 USC § 102

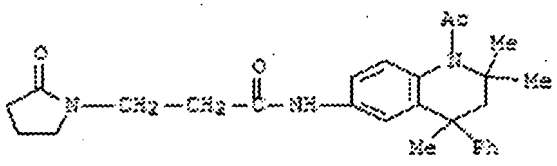
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-13, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Straten, et. al. PCT Int. Application WO 20030004028, filed June 25, 2002. Numerous species that meet the instant claims, a few examples are shown below:

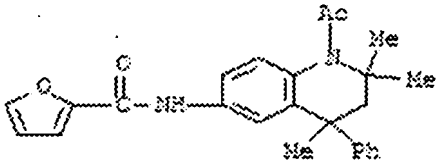
Example 65 pg. 53 where R6 is heterocycloalkyl, R1 is methyl, R2 is methyl, R4 and R5 are H

RN 497064-82-6 CAPLUS
CN 1-Pyrrolidinepropanamide, N-(1-acetyl-1,2,3,4-tetrahydro-3,2,4-trimethyl-4-phenyl-6-quinolinyl)-2-oxo- (9CI) (CA INDEX NAME)



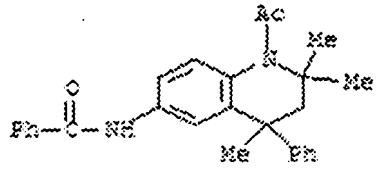
where R6 is heteroaryl

RN 487064-46-9 CAPLUS
CN 2-Furancarboxamide, N-(1-acetyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-4-phenyl-6-quinolinyl)- (9CI) (CA INDEX NAME)



where R6 is phenyl (6C aryl)

RN 487064-30-2 CAPLUS
CN Benzamide, N-(1-acetyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-4-phenyl-6-quinolinyl)- (9CI) (CA INDEX NAME)



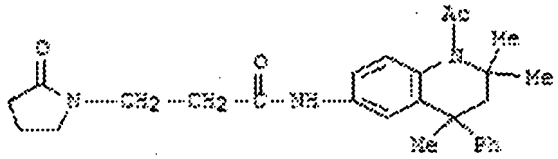
and dozens of others.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

4. Claims 1-13, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Straten, et. al. U.S. Pre-Grant Publication 2004/0236109. Numerous species that meet the instant claims, a few examples are shown below:

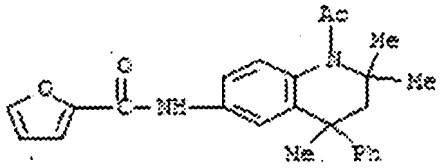
Example 65 pg. 53 where R6 is heterocycloalkyl, R1 is methyl, R2 is methyl, R4 and R5 are H

RN 487068-92-6 CAPLUS
CN 1-Pyrrolidinepropanamide, N-(1-acetyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-4-phenyl-6-quinolinyl)-2-oxo- (9CI) (CA INDEX NAME)



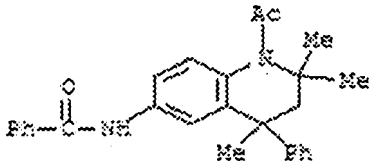
where R6 is heteroaryl

RN 487064-46-0 CAPLUS
CN 2-Furancarboxamide, N-(1-acetyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-4-phenyl-6-quinolinyl)- (9CI) (CA INDEX NAME)



where R6 is phenyl (6C aryl)

RN 487064-30-2 CAPLUS
CN Benzamide, N-(1-acetyl-1,2,3,4-tetrahydro-2,2,4-trimethyl-4-phenyl-6-quinolinyl)- (9CI) (CA INDEX NAME)



and dozens of others.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

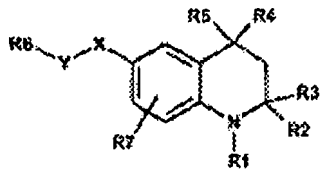
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-13, 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/482,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope substantially and cover the same compounds. The wording is only slightly different and the '707

application is broader but where X is NH and Y is CO the compounds of the instant case are produced. It is noted that some of the same species are present in both applications (see 102(e) rejection).



Formula I

or a pharmaceutically acceptable salt thereof, wherein

R^1 is formyl, (1-6C)alkylcarbonyl or (1-6C)alkylsulfonyl;

R^2 and R^3 are H or (1-4C)alkyl;

R^4 is phenyl, optionally substituted with one or more substituents selected from the group hydroxy, amino, halogen, nitro, trifluoromethyl, cyano, (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (1-4C)alkoxy, (1-4C)(di)alkylamino.

R^5 is (1-4C)alkyl;

Y-X is C(O)-O, $S(O)_2$-O, NHC(O)-O, NHC(S)-O, OC(O)-O, bond-O, C(O)-NH, $S(O)_2$-NH, NHC(O)-NH, NHC(S)-NH, OC(O)-NH, bond-NH, NH-C(O), O-C(O), NH-$S(O)_2$, or O-$S(O)_2$ or X-Y is a bond;

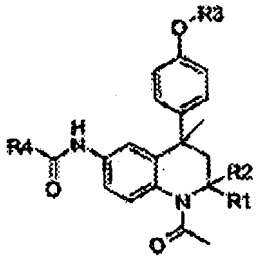
R^6 is H, except for Y-X is a bond, trifluoromethyl, (1-6C)alkyl, 1- or 2-adamantyl(1-4C)alkyl, (2-6C)alkenyl, (2-6C)alkynyl, (3-9C)heteroaryl, (3-6C)cycloalkyl, (2-6C)heterocycloalkyl, (1-4C)alkylthio(1-4C)alkyl, (6-10C)aryl(1-4C)alkyl, (3-9C)heteroaryl(1-4C)alkyl, (3-6C)cycloalkyl(1-4C)alkyl, (2-6C)heterocycloalkyl(1-4C)alkyl, R^8,R^9-aminocarbonyl(1-4C)alkyl, R^8,R^9-amino(1-4C)alkyl, R^8-oxycarbonyl(1-4C)alkyl, R^8-oxy(1-4C)alkyl, R^8-carbonyl(1-4C)alkyl or (6-10C)aryl, whereas if (6-10C)aryl is phenyl, phenyl may be optionally substituted with hydroxy, amino, halogen, nitro, trifluoromethyl, cyano, (1-4C)alkyl, (2-4C)alkenyl, (2-4C)alkynyl, (1-4C)alkoxy, (1-4C)(di)alkylamino, (6-10C)aryl, (6-10C)aryloxy, (6-10C)aryl(1-4C)alkoxy, (3-9C)heteroaryl, (3-9C)heteroaryloxy, (3-9C)heteroaryl(1-4C)alkoxy, (1-4C)alkylcarbonylamino, (1-4C)alkylcarbonyloxy, (3-6C)cycloalkylcarbonyloxy,

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The applications appear to have a common assignee.

6. Claims 1-13, 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/540,335. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope substantially and cover the same compounds. The wording is only slightly different and the '335 application is narrower but the genus produced is nearly identical. It is noted that some of the same species are present in both applications.

Claims

1. A tetrahydroquinoline derivative according to Formula 1,



Formula I

or a pharmaceutically acceptable salt thereof, wherein
R^1 and R^2 are H, Me;
R^3 is (2-6C)heterocycloalkyl(1-4C)alkyl, (2-5C)heteroaryl(1-4C)alkyl, (6C)aryl(1-4C)alkyl, (1-4C)(di)alkylaminocarbonylamino(2-4C)alkyl, (2-6C)heterocycloalkylcarbonylamino(2-4C)alkyl, R^5-(2-4C)alkyl or R^5-carbonyl(1-4C)alkyl;
R^4 is (2-5C)heteroaryl, (6C)aryl, (3-8C)cycloalkyl, (2-6C)heterocycloalkyl or (1-6C)alkyl
R^5 is (di)(1-4C)alkylamino, (1-4C)alkoxy, amino, hydroxy, (6C)arylamino, (di)(3-4C)alkenylamino, (2-5C)heteroaryl(1-4C)alkylamino, (6C)aryl(1-4C)alkylamino, (di)[(1-4C)alkoxy(2-4C)alkyl]amino, (di)[(1-4C)alkylamino(2-4C)alkyl]amino, (di)[amino(2-4C)alkyl]amino or (di)[hydroxy(2-4C)alkyl]amino.

1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The applications appear to have a common assignee.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds, does not reasonably provide enablement for the protracted list of compounds bearing the protracted list of substituents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to the following:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(A) The breadth of the claims: The claims are very broad encompassing a variety of heterocycles (mainly on R4 and R5), bearing multiple substitutions **(B) The nature of the invention:** This is a chemical invention requiring the synthesis of compounds. **(D) The level of one of ordinary skill**: One of ordinary skill is a practicing organic chemist. **(C) The state of the prior art:** Little prior art exists on these complex compounds, however the synthesis will be evaluated on what is known using scientific principles. **(E) The level of predictability in the art:** Chemistry is unpredictable. See In Re Marzocchi and Horton 169 USPQ at 367 paragraph 3. **(F) The amount of direction provided by the inventor, (G) The existence of working examples, and (H) The quantity of experimentation needed to make or use the invention:** The examiner will first consider

the Markush structure I of claim 1, and the inherent limitations of the chemistry used to prepare the examples as well as starting materials and then address the influence of these groups on the utility.

As per MPEP:

> A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

While a vast array of anilines are commercially available for the Skraup reaction. The substituents R4 and R5 apparently have enormous permutations due to their apparent identity as R7 which is actually a list of 10 groups which then further contain the groups R8 and R9 which are themselves more than six groups. Where can one purchase or prepare the required anilines possessing these groups? While apparently a Lewis acid catalyzed version of the Skraup reaction is used to construct the quinoline nucleus, the Skraup has been shown to be sensitive to substituents on the starting aniline (The Chemistry of Heterocyclic compounds: Quinolines PART 1, Jones, Gurnos editor Wiley: New York, 1977 pg. 104-117.) For example the claims are drawn towards

"carbonyloxy" groups which are esters and these groups are "susceptible to decarboxylation" a "further disadvantage" (Jones, ibid. pg. 104 at b.). "Other groups that are modified or eliminated during a Skraup synthesis are the sulphonic acid group, and ether or ester groups." *p*-acetylaniline also fails to undergo the reaction (Jones ibid. pg. 105). One very serious problem is the formation of regioisomeric 5 and 7 quinolines when using meta-substituted anilines, which may or may not be separable.

While some of these limitations are clearly synthetic, perhaps more importantly are the requirements for activity at the FSH receptor. The only information as to what these compounds are doing in the pharmacological sense is the following statement: "Compounds of all examples exhibited an EC50s (IC50s0) value of less than 10^{-5} M in either an agonistic or antagonistic assay set-up or both." A single compound cannot perform as both a full agonist and as an antagonist. Indeed we see that a switch from aganoist to antagonist activity occurs with 4-Cl phenyl (Nicole C. R. van Straten, Twan H. J. van Berkel, Dennis R. Demont, Willem-Jan F. Karstens, Remco Merkx, Julia Oosterom,Ju¨ rgen Schulz, Richard G. van Someren, Cornelis M. Timmers, and Peter M. van Zandvoort "Identification of Substituted 6-Amino-4-phenyltetrahydroquinoline Derivatives: Potent Antagonists for the Follicle-Stimulating Hormone Receptor" Journal of Medicinal Chemistry **2005**, *48*, 1697-1700.) "Aromatic susbstituents in position 6 [R_6 of the instant claims] are preferred..." van Straten ibid. pg. 1698. There is an apparent size constraint on substituents, "space is limited because introduction of an extra t-butyl group in **11** led to a drop in potency" van Straten ibid. pg. 1698.

The factors outlined in *In Re Wands* mentioned above apply here, and in particular As per the MPEP 2164.01 (a): "A conclusion of lack of enablement means that,

based on the evidence regarding each of the above factors, the specification , at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." It is very clear that one could not make/use this very broad invention that has few working examples in this unpredictable art without undue experimentation.

8. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to "methods of fertility regulation", however no clear nexus exists between the compounds described here and "methods of fertility regulation". In the words of van Straten et. al. (ibid. pg. 1700 conclusion) these compounds "may serve as starting points for further optimization to evaluate the feasibility of FSH receptor antagonists as a novel method for contraception."

The effect physiologically of a compound that binds and perturbs the FSH-R (a GPCR) is unclear. While knockout mice are clearly sterile ("Genetic elimination of the alpha subunit in mice by homologous recombination (7) causes complete deficiency of all three glycoprotein hormones, and animals of both sexes are not only sterile but also hypothyroid." M. Ram Sairam and Hanumanthappa Krishnamurthy "The Role of Follicle-Stimulating Hormone in Spermatogenesis: Lessons from Knockout Animal Models" Archives of Medical Research 32 (2001) 601–608.) Mutants which presumably have some receptor function (as in the instant case) "exhibit delayed sexual maturity and

reduced fertility". The real problem here is that this receptor is a GPCR with a vast number of binding sites and conformations each of which may be associated with a distinct physiological outcome. One reviewer has summarized the situation this way (Terry Kenakin and Ongun Onaran "The ligand paradox between affinity and efficacy: can you be there and not make a difference?" *TRENDS in Pharmacological Sciences* **2002**, *23*, 275-280):

"A probabilistic model of protein conformation can be used to quantify the probability of various receptor conformations and the effect of ligand binding on those conformations. The basic idea behind the probabilistic model is that the function of a receptor protein is not assigned to particular conformations of the receptor. Instead, the function arises as a result of ligand-induced perturbation of the distribution of conformational states over the conformational space of the receptor.....**The foregoing discussion leads to the general conclusion that if a ligand binds to the receptor, it most probably will produce a bias in the conformations of the receptor ensemble** [i.e. it will change the receptor by its presence (Fig. 3)]. Therefore, this suggests that all ligands with macro-affinity should be extensively studied for pharmacological activities other than simple G-protein activation because various physiological activities have been defined that are mediated by conformations not necessarily related only to G-protein activation..... Ligand activities that are not related to a standard G-protein-mediated physiological response **might have therapeutic utility**.

Here we have exactly this situation, namely a ligand with affinity, but no known function, which as Kenakin et. al. concluded "...the discovery of macro-affinity of a ligand for a receptor should be considered only a starting point for the optimal exploitation of a drug for therapeutic utility." One reviewer summarized the state of the art this way: Only in the clinic will the question of whether small molecule LHR and FSHR modulators will be successful as fertility-regulating agents be answered." (Guo, Tao "Small molecule agonists and antagonists for the LH and FSH receptors." Expert Opinion on Therapeutic Patents 2005 15(11) 1555-1564, conclusions.) There is no successful use of these compounds in an animal model and no clear correlation between antagonism of this receptor and a therapeutic outcome, thus undue experimentation would be required.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

RITA DESAI
PRIMARY EXAMINER